UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

DENISE MCGRATH,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC., et al.

Defendants.

Civ. No. 18-CV-02134-RJD-VMS

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS OF DEFENDANTS BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER CORPORATION, AND BAYER HEALTHCARE LLC

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Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer HealthCare LLC (collectively "Bayer") move to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(2) and (6). Plaintiff Denise McGrath ("Plaintiff") fails to plead personal jurisdiction over Bayer and further fails to state a claim for either of her two, warning-based causes of action—strict liability or negligence—regarding Bayer's FDA-approved product Magnevist.

Since Plaintiff fails to plead facts to show that Bayer has the requisite minimum contacts with New York relevant to this lawsuit, and Bayer resides out of state, Bayer requests dismissal. As Plaintiff concedes, general personal jurisdiction is not present: all Bayer entities are incorporated and headquartered outside of New York. Nor has Plaintiff demonstrated specific, case-linked jurisdiction over Bayer, since Plaintiff merely relies on the "stream of commerce" theory of personal jurisdiction—a claim that Bayer sold its products in the national marketplace through a third-party distributor. Particularly given the Supreme Court's recent ruling in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S.Ct. 1773 (2017), the "stream of commerce" theory is legally defunct and cannot support suit in New York. Nor does Plaintiff's alleged residency in New York confer jurisdiction, since it is now settled law that alleging "mere injury to a forum resident" does not establish jurisdiction over out-of-state defendants. *Walden v. Fiore*, 571 U.S. 277, 289-290 (2014).

Plaintiff also fails to show that her claims, all of which object to Magnevist's warning label, are not preempted. Plaintiff contends that Bayer should have added a warning to Magnevist's label stating that gadolinium retention from Magnevist use posed health risks for persons like Plaintiff with normal renal function. But Plaintiff's claims rely on Bayer's conduct before the FDA approved the Magnevist label, and claims relying on pre-approval conduct are

preempted. Further, contrary to federal requirements, Plaintiff pleads no facts showing Bayer ever could have "independently change[d] its [product] label," without the FDA's prior approval, to incorporate her desired warning. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 43 (1st Cir. 2015). That is particularly true because the FDA recently approved Magnevist product labeling stating that "clinical consequences of gadolinium retention have not been established in patients with normal renal function," which is directly contrary to Plaintiff's medical theory. And publicly-available FDA documents incorporated into the Complaint show that, if Bayer had attempted to make Plaintiff's requested change, the FDA would have rejected it. Consequently, Plaintiff fails to plead facts showing her claims can escape preemption.

Plaintiff also fails to identify an injury that can support either her negligence or strict liability claim. Plaintiff's allegation that she experienced "gadolinium retention," *i.e.*, that trace amounts of gadolinium remained in her body after using Magnevist, is not a legally cognizable injury under New York law. And Plaintiff pleads no facts showing any other alleged injuries were reasonably foreseeable. She also pleads both her causes of action in a vague, unclear way that does not satisfy Rule 8(a) and associated precedent.

Accordingly, Bayer requests dismissal with prejudice of both causes of action.

I. FACTUAL AND PROCEDURAL BACKGROUND

Magnevist is an FDA-approved gadolinium-based contrast agent ("GBCA") administered intravenously by medical professionals to enhance the quality of magnetic resonance imaging ("MRI") to diagnose serious conditions, such as cancer, strokes, and aneurysms. Plaintiff filed suit on November 1, 2017, bringing claims related to Magnevist.

A. Initial Complaint: Unrecognized "Gadolinium Deposition Disease"

Plaintiff's original complaint alleged that Magnevist[1] caused problems Plaintiff called "Gadolinium Deposition Disease." *See* Dkt. No. 1 at pp.1-2, *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, No. 1:18-cv-06375 (11/01/2017) (hereinafter "Initial Complaint"). "Gadolinium Deposition Disease," which is not a "disease" recognized by the medical community, is a catch-all term used by plaintiffs for a nonspecific collection of symptoms supposedly experienced by some patients who use GBCAs. The symptoms alleged by Plaintiff in her original complaint included a "feeling of dehydration, anxiousness, digestive disturbances, food intolerance, and sensitivity to other medications and supplements." Initial Compl. p.10.

B. Amended Complaint: Gadolinium "Retention," "Fibrosis," and "Related Injuries"

Plaintiff's First Amended Complaint ("Complaint" or "Compl.") omits any reference to "Gadolinium Deposition Disease," instead declaring that Plaintiff's "primary injury" is "gadolinium ***retention***," meaning that trace amounts of gadolinium remained in her body after using Magnevist. *See* Compl. pp.1-2 ¶ 4 (emphasis added). Plaintiff also claims that gadolinium retention "resulted in fibrosis in her organs, skin, and bones . . . and related injuries." Compl. at p.5 ¶ 24. Plaintiff never says what those "related injuries" are. *Id.*

Plaintiff's claim that any negative medical consequences result from alleged trace retention of gadolinium in patients with normal kidney function is starkly at odds with the FDA's expressed view, reaffirmed after the filing of Plaintiff's Initial Complaint, that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function," which, as alleged, includes Plaintiff.[2] Ex. A, 12/19/2017 FDA Safety Announcement

[1] Plaintiff also included reference to another gadolinium-based contrast agent, Gadavist, in the original complaint, but in the First Amended Complaint makes no mention of that product.

[2] District courts in the Second Circuit frequently take judicial notice of documents on the FDA's website, and Bayer requests that the Court do so here. *See, e.g.*, *Porrazzo v. Bumble Bee Foods,*

at 2[3], https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm; *see also* Compl. p.5 ¶ 24 ("Plaintiff Denise McGrath had normal kidney function at the time she was injected with these GBCAs.").

C. Procedural Background: No Allegation of Bayer's In-State Acts Related to This Suit

Plaintiff's Initial Complaint was designed to establish personal jurisdiction over Bayer in California, and did not allege that this suit arose from Bayer's actions in New York. Initial Compl. pp.2-4, 10. In place of the generic allegations concerning California in the Initial Complaint, *id.*, Plaintiff's Amended Complaint now provides general, threadbare allegations of Bayer's unspecified business in New York, with no details connecting any supposed New York activities to the facts giving rise to this lawsuit. *See, e.g.*, Compl. p.4 ¶¶ 19-20 (arguing that "[t]his Court has personal jurisdiction over Defendants" because each defendant is "licensed to conduct ***and/or*** is systematically and continuously conducting business in this state" (emphasis added)).

II. ARGUMENT

A. Plaintiff Fails to Plead Minimum Jurisdictional Contacts between Bayer and New York

The claims against the Bayer entities should be dismissed for lack of personal jurisdiction. "To defeat a motion to dismiss for lack of personal jurisdiction, a plaintiff must

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LLC, 822 F. Supp. 2d 406, 412 (S.D.N.Y. 2011) (taking "judicial notice of . . . documents" "[b]ecause the documents . . . are all publicly available on the FDA website"); *In re Zyprexa Prod. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) ("Public documents issued by government agencies such as the Food and Drug Administration ('FDA') may also be considered" in deciding a motion to dismiss). Judicial notice of these documents is appropriate under Fed. R. Evid. 201(b) because material on FDA's website is "capable of accurate and ready determination by resort to" FDA itself, a "source[] whose accuracy cannot be reasonably questioned." *See Porrazzo*, 822 F. Supp. 2d at 411-12.

[3] The exhibits named herein are exhibits to the Declaration of Jennifer L. Greenblatt.

make a prima facie showing that jurisdiction exists." *Charles Schwab Corp. v. Bank of Am. Corp.*, 883 F.3d 68, 81 (2d Cir. 2018) (quotation marks and brackets omitted). "Such a showing entails making legally sufficient allegations of jurisdiction, including an averment of facts that, if credited, would suffice to establish jurisdiction over the defendant." *Id.*

In particular, a plaintiff must "demonstrate that the exercise of personal jurisdiction comports with [constitutional] due process." *Id.* at 82. Neither general nor specific personal jurisdiction—the two constitutionally permissible categories of personal jurisdiction—may be exercised over Bayer in this case. *See BNSF Railway Co. v. Tyrell*, 137 S. Ct. 1549 (2017); *Daimler AG v. Bauman*, 571 U.S. 117 (2014); *Bristol-Myers Squibb Co. v. Super. Ct. of Cal., S.F. Cty.*, 137 S. Ct. 1773 (2017).

1. Plaintiff Concedes General Jurisdiction Does Not Exist over Bayer

Plaintiff concedes that there is no general, all-purpose personal jurisdiction over the Bayer entities, which are all non-New York companies.[4] That stands to reason: general jurisdiction exists only when a defendant is "essentially at home in the forum State," which almost universally requires that a company's "incorporation" or "principal place of business" be in the forum state. *See Daimler AG v. Bauman*, 571 U.S. 117, 139 n.19 (2014). Here, Plaintiff emphasizes that no Bayer defendant is incorporated or headquartered in New York. Compl. p.4 ¶ 18 ("all Defendants are entities organized in states other than the State of New York[and] all Defendants have their principal place of business in a state other than the State of New York"). And, as the Supreme Court has clarified, a company's mere "in-state business . . . does not suffice to permit the assertion of general jurisdiction." *BNSF*, 137 S. Ct. at 1559. Thus, there is no colorable argument for general jurisdiction over the Bayer defendants.

[4] Plaintiff's counsel conceded this point in the meet-and-confer process.

2. Plaintiff's Allegations Fail to Demonstrate Specific Jurisdiction over Bayer

Plaintiff also fails to prove specific, case-linked jurisdiction, which requires a "relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 571 U.S. 277, 287 (2014). It is beyond dispute that "mere injury to a forum resident" does not establish jurisdiction over out-of-state defendants. *Id.* at 290.

a. Plaintiff's Stream-of-Commerce Allegations Fail to Demonstrate Specific Jurisdiction

Plaintiff fails to plead facts showing jurisdiction because she relies on vague allegations that Bayer "introduce[d] Magnevist into interstate commerce" through the drug distributor McKesson—and that "stream-of-commerce" argument is legally defunct. *See* Compl. pp.2-3 ¶¶ 7-9, 12. Particularly in light of the Supreme Court's recent decisions in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S.Ct. 1773 (2017) and *Walden v. Fiore*, 571 U.S. 277 (2014), numerous courts around the country have soundly rejected such stream-of-commerce theories. *See, e.g.*, *Montgomery v. Airbus Helicopters, Inc.*, 414 P.3d 824, 833 (Okla. 2018) (after *Walden* and *Bristol-Myers*, "any 'stream of commerce' test . . . cannot establish Oklahoma jurisdiction"); *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 780 (3d Cir. 2018) ("we decline to adopt the . . . stream-of-commerce theory of specific personal jurisdiction"). And rejection of stream-of-commerce theory is consistent with past rulings from courts in this Circuit. *See, e.g.*, *Bensusan Rest. Corp. v. King*, 937 F. Supp. 295, 301 (S.D.N.Y. 1996) ("[P]lacing a product into the stream of commerce . . . without more, it is not an act purposefully directed toward the forum state."), *aff'd*, 126 F.3d 25 (2d Cir. 1997); *Gale v. Smith & Nephew PLC*, No. 12-cv-3614 VB, 2015 WL 328127, at *3 (S.D.N.Y. Jan. 20, 2015) ("Placing the System in New York's stream of commerce, without additional purposeful activity,

may not be enough to establish a substantial connection with New York consistent with due process.").

Bristol-Myers and *Walden* clarify that personal jurisdiction requires ***a defendant's own contacts*** with the ***forum state***; a defendant's mere placement of a product into the hands of a third-party distributor who then places it in the national stream of commerce reaching a forum resident will not suffice. In *Bristol-Myers*, the Supreme Court rejected the "last ditch contention" that an out-of-state pharmaceutical company's contacts with McKesson Corporation—a California-based drug distributor—created personal jurisdiction over the pharmaceutical company in California. *Bristol-Myers*, 137 S. Ct. at 1783. The opinion relied on *Walden*'s rule that "a defendant's relationship with a . . . third party . . . is an insufficient basis for jurisdiction." *Walden*, 571 U.S. at 286. Instead, personal jurisdiction requires a "relationship among the defendant, the forum, and the litigation," and "the relationship must arise out of contacts that the defendant *himself* creates with the forum State." *Id.* at 283-84 (quotation marks omitted; emphasis in original). *Walden* also held that "mere injury to a forum resident is not a sufficient connection to the forum" to create personal jurisdiction. 571 U.S. at 290. Both of *Walden*'s rules reflect that "[t]he proper question is not where the plaintiff experienced a particular injury or effect but whether ***the defendant's conduct*** connects him ***to the forum*** in a meaningful way." *Id.* at 290 (emphasis added).

Following *Bristol-Myers* and *Walden*, numerous courts have rejected personal jurisdiction over defendants whose products allegedly reached forum residents through third-party distributors selling in the national stream of commerce. In *Montgomery v. Airbus Helicopters, Inc.*, the Supreme Court of Oklahoma, citing *Bristol-Myers* and *Walden*, rejected an Oklahoma resident's claim of personal jurisdiction over an out-of-state product manufacturer in a

wrongful death lawsuit, explaining that "subsequent to *Bristol-Myers*, . . . we must conclude that any 'stream of commerce' test . . . cannot establish Oklahoma jurisdiction." 414 P.3d at 833. And in *Shuker v. Smith & Nephew*, the Third Circuit held that a Pennsylvania court could not exercise personal jurisdiction over a Pennsylvania plaintiff's claims against an out-of-state medical device manufacturer, explaining that, per *Bristol-Myers*, "the bare fact that a non-resident defendant contracted with a resident distributor is not enough to establish personal jurisdiction in the State."[5] 885 F.3d at 780 (brackets omitted). Numerous other courts have followed suit.[6]

In this case, Plaintiff similarly alleges that Bayer placed Bayer's product, Magnevist, into the hands of McKesson—a distributor ***not even residing in New York***— thereby "introducing Magnevist [] into interstate commerce." Compl. p.3 ¶ 13. That allegation fails to establish jurisdiction in light of *Bristol-Myers* and *Walden*, as illustrated in *Montgomery* and *Shuker*. Plaintiff openly "alleges that McKesson distributed the Magnevist . . . that was injected into Plaintiff," even though an out-of-state manufacturer's relationship with McKesson, a third party, was irrelevant in *Bristol-Myers*. *See* Compl. p.3 ¶ 12. Other allegations just restate that Bayer did nothing more than sell Magnevist to McKesson for marketing in the national stream of commerce:

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[5] Although not explicitly stated in the Third Circuit's opinion, underlying case documents make clear that the plaintiffs in *Shuker* were Pennsylvania residents who used the products in Pennsylvania. *See* Plaintiff's Mem. of Law in Opp. to Def. Mot. to Dismiss, Case No. 5:13-cv-6158, 2014 WL 12815459 (E.D. Pa. May 15, 2014) ("Walter Shuker underwent a right total hip arthroplasty at the Surgical Institute of Reading in Reading, Pennsylvania."); Dkt. 101 p.1, Third Amended Compl., *Shuker v. Smith & Nephew Inc.*, No. 5:13-cv-6158 (E.D. Pa. 8/27/15) (clarifying that plaintiffs are Pennsylvania residents).

[6] *See, e.g.*, *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1129, 1137-38, 1214 (D.N.M. 2017) (rejecting in-state plaintiffs' arguments for personal jurisdiction over out-of-state tobacco manufacturer that had not "directed its activities at" plaintiffs outside its home state); *A.T. through Travis v. Hahn*, --- F. Supp. 3d ---, No. 4:18-CV-01139, 2018 WL 5278699, at *4-5 (E.D. Mo. Oct. 24, 2018) (rejecting stream-of-commerce theory on authority of *Bristol-Myers*).

> Bayer Healthcare Pharmaceuticals Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist ***into interstate commerce***, either directly ***or indirectly through third parties*** or related entities.

Compl. p.2 ¶ 7 (emphasis added); *see also* Compl. pp.2-3 ¶¶ 8-9 (similar allegations for Bayer Corporation and Bayer HealthCare LLC); Compl. p.5 ¶ 23 (alleging that "Defendants" "developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold the referenced GBCAs ***in interstate commerce***" (emphasis added)). Plaintiff alleges she used Magnevist in New York, Compl. p.4 ¶ 20, but, as noted, "mere injury to a forum resident is not a sufficient connection to the forum" to create personal jurisdiction, *Walden*, 571 U.S. at 290, and both *Montgomery* and *Shuker* involved injuries to forum residents in their home states, which did not create personal jurisdiction over foreign manufacturers selling products in national commerce. Plaintiff alleges nothing that ***Bayer itself*** did to ***target New York*** in a way related to her suit, which precludes personal jurisdiction.

In sum, Plaintiff's stream-of-commerce allegations cannot establish personal jurisdiction over Bayer, since they fail to show a "relationship among the defendant, the forum, and the litigation," *Walden*, 571 U.S. at 284, and focus instead on the allegation that Bayer's product happened to end up in a New Yorker's hands by way of a third-party distributor and the national stream of commerce. After *Bristol-Myers* and *Walden*, that is plainly not enough.

b. Plaintiff's Allegations as to Bayer's Tarrytown, NY Facility Are Irrelevant Since They Are Unrelated to This Suit

Plaintiff further claims, in one sentence, that "[t]he Bayer Defendants operated at [sic] facility in Tarrytown, New York." Compl. p.4 ¶ 20. Plaintiff provides no explanation for how the facility is "***suit-related conduct***" in New York, as is required for personal jurisdiction. *Charles Schwab Corp. v. Bank of Am. Corp.*, 883 F.3d 68, 83–84 (2d Cir. 2018) (emphasis added)

(quoting *Walden*, 571 U.S. at 284). That is unsurprising because, as explained in the attached declaration of Keith Abrams:

- No Bayer defendant ***ever*** manufactured Magnevist in Tarrytown, NY. *See* Decl. of Keith Abrams.
- No Bayer defendant ***ever*** located Magnevist sales or marketing representatives at any facility the Bayer defendants operated in Tarrytown, NY. *See id.*
- No Bayer defendant ***ever*** researched, tested, or distributed Magnevist at any facility operated by the Bayer defendants in Tarrytown, or conducted clinical trials of Magnevist there. *See id.*

Plaintiff's bare-bones allegations of the existence of a Tarrytown, NY facility "are irrelevant to the jurisdictional analysis, because they are not sufficiently related to" the claims in this suit.[7] *Charles Schwab*, 883 F.3d at 83 (quotation marks omitted).

c. Plaintiff's Remaining Allegations Are Also Irrelevant

Plaintiff's other purported bases of jurisdiction are nonspecific and conclusory, and fail to show how any particular Bayer activity in New York relates to her claims whatsoever.

- Plaintiff alleges Bayer is "registered to do business in the State of New York." Compl. p.4 ¶ 20. But "an exercise of general personal jurisdiction based on registration alone would be counter to the principles of due process," *Wilderness USA, Inc. v. DeAngelo Bros. LLC*, 265 F. Supp. 3d 301, 313 (W.D.N.Y. 2017).
- Plaintiff alleges unspecified in-state "clinical trials and other research." Compl. p.4 ¶ 20. These allegations, unaccompanied by any factual detail, are not an "averment ***of facts*** that, if credited, would suffice to establish jurisdiction over the defendant."[8] *Charles*

[7] Further, Plaintiff cannot argue that "the strength of the requisite connection between [New York] and the specific claims at issue is relaxed if the defendant has extensive forum contacts that are unrelated to those claims," since the Supreme Court squarely rejected that approach in *Bristol*-Myers. 137 S. Ct. at 1781 ("Our cases provide no support for this approach . . . .").

[8] Many of Plaintiff's allegations are entirely conclusory and present no facts at all. For example, Plaintiff asserts that this Court "has personal jurisdiction over [Bayer] . . . because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities." Compl. pp.2-3 ¶¶ 7-9. But Plaintiff says nothing about how Bayer "purposely availed itself" of New York law. *See also* Compl. p.5 ¶ 23 (alleging that "Defendants do substantial business in this state and within this District," but without specifying the purported "business" or how it relates to the case).

Schwab, 883 F.3d 68, 81 (2d Cir. 2018) (emphasis added). Further, Plaintiff does not explain how these actions are "***suit-related conduct***," as is required for personal jurisdiction. *Id.* at 83–84; *see Dyson v. Bayer Corp.*, No. 4:17-cv-2584, 2018 WL 534375, at *4 (E.D. Mo. Jan. 24, 2018) (holding that "the individual plaintiffs' claims are too attenuated from [clinical trials] to prove specific, 'case-linked' personal jurisdiction" in state where trials were held).

- Plaintiff makes numerous general allegations against "Defendants" without specifying which actions any particular defendant took. *See, e.g.*, Compl. p.5 ¶ 23 ("Defendants marketed, advertised, and distributed the dangerous product in this District"). That is impermissible because "[t]he requirements of [personal jurisdiction] . . . must be met as to ***each defendant***," and a plaintiff may not "attribute [one defendant's] contacts to [another] by considering the 'defending parties' together and aggregating their forum contacts." *Rush v. Savchuk*, 444 U.S. 320, 331-32 (1980) (emphasis added).

d. Bayer Requests Dismissal or Transfer to the District of Delaware to Cure Jurisdictional Defects

Since Plaintiff fails to prove personal jurisdiction over any Bayer entities, Bayer respectfully requests that the Court dismiss the Complaint in its entirety. *Sinoying Logistics Pte Ltd. v. Yi Da Xin Trading Corp.*, 619 F.3d 207, 216 (2d Cir. 2010) (affirming district court's *sua sponte* dismissal for lack of personal jurisdiction).

Alternatively, Bayer requests transfer to the District of Delaware pursuant to 28 U.S.C. § 1631 to cure this jurisdictional defect. *See Zaveri v. Condor Petroleum Corp.*, No. 08-cv-6554, 2009 WL 2461092, at *4 (W.D.N.Y. Aug. 10, 2009) (transferring case pursuant to 28 U.S.C. § 1631 where personal jurisdiction was lacking). Because general jurisdiction will exist there over Bayer HealthCare Pharmaceuticals Inc. and Bayer HealthCare LLC, which are incorporated in Delaware, *see Daimler*, 571 U.S. at 139 n.19 (noting that general jurisdiction typically exists in state of incorporation), Bayer will waive personal jurisdiction in Delaware over Bayer Corporation, thus curing all jurisdictional issues.

B. <u>As Pled, Plaintiff's Claims Are Preempted</u>

Plaintiff's claims all rest on the assumption that Magnevist's FDA-approved label was inadequate because it lacked her desired warning: that gadolinium retention causes injuries to

persons with normal kidney function.[9] However, given the FDA's "onerous and lengthy" "drug approval process," plaintiffs must fulfill several requirements to avoid preemption of failure-to-warn claims objecting to an FDA-approved drug label. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 35 (1st Cir. 2015).

A plaintiff faces three separate requirements to avoid preemption of failure-to-warn claims targeting FDA-approved drug labels; here, Plaintiff fails to meet all three. ***First***, a plaintiff cannot object to a label based on conduct arising before the FDA approves that label—for example, by claiming the defendant should have given the FDA more information to decide whether to approve the label. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001); *In re Celexa*, 779 F.3d at 36. ***Second***, "the plaintiff must show that the defendant[] could unilaterally change the label" after initial FDA approval of the label by alleging that the defendant possessed ***newly acquired information*** unknown to the FDA when it approved the label. *Byrd v. Janssen Pharm., Inc.*, --- F. Supp. 3d ---, No. 114CV0820, 2018 WL 4554490, at *5 (N.D.N.Y. Sept. 21, 2018) (emphasis added) (ellipsis and quotation marks omitted); *see also In re Celexa*, 779 F.3d at 41-42. ***Third***, even where the defendant had newly acquired information permitting a unilateral label change, a plaintiff's claim is still preempted upon "clear evidence" that the FDA would have rejected the defendant's unilateral label change. *Byrd*, 2018 WL 4554490, at *5 (quotation marks omitted).

Since Plaintiff fails all three of these requirements for avoiding preemption, her claims should be dismissed at the motion-to-dismiss stage—a juncture where courts often dismiss preempted claims. *See, e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672-73

[9] Plaintiff's claims fail to the extent those claims are based on mere "retention" of gadolinium, rather than some further alleged harm, since "retention" is not a legally cognizable injury. *See infra* Sec. II.C.1.a.

(S.D.N.Y. 2017) ("It is well-established that preemption may be analyzed and decided at the motion to dismiss stage."); *In re Celexa*, 779 F.3d at 43 (holding pharmaceutical drug claims preempted at motion-to-dismiss stage); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (same).

1. Plaintiff's Claims Are Preempted to the Extent Plaintiff Alleges that Bayer Failed to Communicate Information to the FDA before Approval of Magnevist's Initial Label

Plaintiff cannot rely on any allegations that Bayer failed to inform the FDA of information known before Magnevist's 1988 initial approval (*e.g.*, Compl. pp.7-8, ¶¶ 36, 40) because "[f]ederal law preempts state-law claims based on a defendant's failure to communicate with the FDA." *McGee v. Boehringer Ingelheim Pharm., Inc.*, No. 4:16-CV-2082, 2018 WL 1399237, at *4 (N.D. Ala. Mar. 20, 2018). When the FDA initially approved Magnevist in 1988, the agency conducted an "onerous and lengthy" process requiring Bayer to "submit the labeling proposed to be used for" Magnevist. *In re Celexa*, 779 F.3d at 35-36 (quotation marks omitted). The FDA approved Magnevist's initial label, including its warning; at the time of approval, Bayer was required to distribute Magnevist with precisely that label. *See id.* ("After approval, the manufacturer may distribute the drug without violating federal law as long as it uses the FDA-approved label.").

Claims that Bayer failed to inform the FDA of any risks before it approved Magnevist's label are preempted for numerous reasons. In *Buckman*, plaintiffs claimed that a manufacturer's "fraudulent representations to the FDA" led the FDA to approve harmful products. 531 U.S. at 346-348. The Supreme Court held those claims were "pre-empted by[] federal law," since "the federal statutory scheme amply empowers the FDA," not private plaintiffs, "to punish and deter fraud against the [FDA]." *Id.* Accordingly, any claim "that [a defendant] should have alerted the FDA about [a] risk *before* . . . approval . . . is preempted because the claim is essentially one of

failure to communicate with the FDA." *McGee*, 2018 WL 1399237, at *4 (granting motion to dismiss).

Further, Plaintiff may not claim Magnevist's label was inadequate when approved by the FDA since Bayer could not have changed the initially-approved label unilaterally. "[W]hen a party cannot satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are pre-empted." *Mensing*, 564 U.S. at 623–24. Because "manufacturers lack the authority to alter . . . a label's warnings at the time the [initial FDA] approval process concludes," "federal law preempts all . . . failure to warn and design defect claims" based on defendants' actions taken "pre-FDA approval."[10] *Utts*, 251 F. Supp. 3d at 660.

Here, Plaintiff impermissibly relies on allegations that Bayer failed to communicate information to the FDA before Magnevist's approval, resulting in an improper initial Magnevist label. *See Buckman*, 531 U.S. 341; *Utts*, 226 F. Supp. 3d at 184. Plaintiff broadly alleges that Bayer provided inadequate safety information during "the years that [Bayer] manufactured . . . [Magnevist,]" Compl. p.6 ¶ 26, including in the time "***prior to marketing***" Magnevist when FDA approval had not yet occurred, *see* Compl. p.14 ¶ 65 (emphasis added). Plaintiff's argument relies on alleged scientific developments before 1988, the year of Magnevist's approval and entry to the market, *see* Compl. p.8 ¶ 38 ("Magnevist . . . receiv[ed] FDA approval in 1988"). Plaintiff alleges that "manufacturers . . . have known since the 1980s that their drugs could cause retention of toxic gadolinium." Compl. p.7 ¶ 35. In particular, Plaintiff contends that "deposition

[10] Moreover, FDA approval of a drug label reflects "the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively," *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184 (S.D.N.Y. 2016), and the FDA's judgment that "the proposed label is not false or misleading in any particular." *In re Celexa*, 779 F.3d at 36 (quotation marks omitted). Claims objecting to a drug label as initially approved by the FDA thus impermissibly target the agency itself. *Utts*, 226 F. Supp. 3d at 184.

of toxic gadolinium in tissues has been described in animal models ***since at least 1984***." Compl. p.8 ¶ 40 (emphasis added). Plaintiff's allegations that Bayer should have acted on information "prior to marketing" Magnevist, Compl. p.14 ¶ 65—at a time before the FDA approved Magnevist's initial label—must be disregarded because that argument is preempted.

2. Plaintiff Fails to Plead "Newly Acquired Information" that Would Allow Bayer to Unilaterally Add Plaintiff's Desired Warning After Magnevist's Approval

Plaintiff also fails to show Bayer could have unilaterally added Plaintiff's desired warning of health risks from gadolinium retention to Magnevist's label at any time ***after*** the FDA's initial approval of the product—which means her claims are entirely preempted. "[W]hen a party cannot satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are pre-empted." *Mensing*, 564 U.S. at 623–24. That means Plaintiff must show that "the defendants could ***unilaterally*** change the label without FDA approval" to escape preemption. *Byrd*, 2018 WL 4554490, at *5 (emphasis added, ellipses omitted). And "federal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the ["Changes Being Effected," or "CBE"] regulation." *Utts*, 226 F. Supp. 3d at 184-85; *see also Mensing*, 564 U.S. at 624 (explaining that *Wyeth v. Levine*, 555 U.S. 555 (2009), held that a failure-to-warn claim "was not pre-empted because it was possible for Wyeth . . . to comply with both state and federal law" using "the CBE regulation"). Thus, Plaintiff must allege facts plausibly showing that Bayer could have "use[d] the CBE procedure to alter the FDA label in the manner that [Plaintiff] allege[s] is necessary." *In re Celexa*, 779 F.3d at 43.

Plaintiff does not show that Bayer could have added Plaintiff's desired warning—that gadolinium retention causes ***adverse health effects*** in patients with normal kidney function—using the CBE regulation. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A) (CBE regulation). "The CBE

procedure is only available to make changes . . . based on 'newly acquired information'" discovered ***after*** a label receives initial FDA approval. *In re Celexa*, 779 F.3d at 41–42 (emphasis added). And that "new[] information" must provide "reasonable evidence of a causal association" of "a clinically significant" "adverse reaction[]" linked to a drug. *See* 21 C.F.R. § 201.57(c)(6)(i). To be "clinically significant," the adverse reaction must "have significant impact on therapeutic decisionmaking," *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006), such as a risk that is "potentially fatal, [or otherwise] serious," 21 C.F.R. § 201.57(c)(6)(i).

The FDA's repeated, emphatic statements about GBCAs show that there has never been "information" demonstrating a "clinically significant" "adverse reaction[]" that would allow Bayer to add Plaintiff's desired warning. In 2018, the FDA approved Magnevist's current label stating that "clinical consequences of gadolinium retention ***have not been established*** in patients with normal renal function,"[11] which includes Plaintiff, *see* Compl. p.2 ¶ 5 (claiming normal renal function). That statement is consistent with the FDA's prior public statements that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function." Ex. A, 12/19/2017 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm; *see also* Ex. C, 7/27/2015 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm455386.htm at 1, (stating that, while "trace amounts of gadolinium may stay in the body long-term," the "[a]vailable information does not identify any adverse health effects.").

Unsurprisingly, the Complaint includes no reference to "newly acquired information," at any time, showing that gadolinium retention from Magnevist causes any "clinically significant"

[11] *See* Ex. B, 7/25/2018 Revised Magnevist label at 4 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf.

"adverse reaction[]" for patients with normal kidney function. *See In re Celexa*, 779 F.3d at 41-42; 21 C.F.R. § 201.57(c)(6)(i). Plaintiff's list in the Complaint of purported scientific developments, all of which pre-date the FDA's 2018 approval of the label statements that directly contradict Plaintiff's desired warning, *see* Compl. pp.5-13, falls far short of showing Bayer could have met the CBE standard to add Plaintiff's desired warning to Magnevist's label:

- Plaintiff names no scientific development suggesting gadolinium retention from use of Magnevist caused a negative symptom that was a "clinically significant" adverse reaction in persons with normal kidney function. *See* Compl. pp.5-13.

- Most of Plaintiff's listed scientific developments relate to mere ***retention*** of trace amounts of gadolinium in patients' bodies after using GBCAs—not to any further adverse reaction caused by retention, *see* 21 C.F.R. § 201.57(c)(6)(i), much less a "clinically significant" one with "significant impact on therapeutic decisionmaking," *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006). *See, e.g.*, Compl. pp.9-10 ¶¶ 45-47 (alleging documentation of retention of gadolinium in humans); pp.11-13 ¶¶ 55-59 (alleging studies finding evidence of retained gadolinium, and regulatory action regarding retained gadolinium).

- Other developments relate to general facts about GBCAs, and have nothing to do with any purported direct effects on humans. *See, e.g.*, Compl. pp.7-8 ¶¶ 37-41 (commenting on strength of gadolinium chelates and stability); pp.8-9 ¶¶ 40-44 (discussing deposition of gadolinium in animals).

- Plaintiff also discusses nephrogenic systemic fibrosis (NSF), which is not relevant to her lawsuit premised on her normal kidney function since NSF affects only persons with kidney impairments. *See, e.g.*, Compl. pp.10-11 ¶¶ 49-53.

- The remaining "facts" are unsupported generalizations that on their face fail the pleading requirements of *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) ("legal conclusions . . . . must be supported by . . . . well-pleaded factual allegations"). *See, e.g.*, Compl. p.10 ¶ 48 ("Defendants have continuously failed to warn consumers").

- Nowhere does Plaintiff allege that, in approving Magnevist's 2018 label stating "clinical consequences of gadolinium retention have not been established in patients with normal renal function," the FDA was not provided any information alleged in the Complaint.

Plaintiff thus fails to plead that the claims against Bayer can escape preemption, and the Complaint should be dismissed. *See Utts*, 226 F. Supp. 3d at 184-85 (dismissing claims as preempted); *In re Celexa*, 779 F.3d at 43 (affirming dismissal where claims were preempted).

3. Clear Evidence Shows the FDA Would Have Rejected Plaintiff's Desired Warning Had Bayer Added It Using the CBE Regulation

Even if Plaintiff ***had*** pled that Bayer could have changed Magnevist's label using the CBE regulation, which she has not, she still fails to plead facts showing that the FDA would have allowed the labeling change she seeks, so her claims are preempted nonetheless. *See, e.g.*, *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 812 (7th Cir. 2018) ("[E]ven if GSK had newly acquired information [satisfying the CBE regulations], GSK can still succeed on its preemption defense if there is clear evidence that the FDA would have rejected the . . . warning . . . ."). Though manufacturers can change label text unilaterally with the CBE regulation, "the FDA can [later] reject CBE submissions and require manufacturers to revert to the prior version of the label." *Id*. A tort claim requiring a label change is preempted if "there [is] *clear evidence* the FDA would have rejected the proposed change in the drug's label." *See id.*; *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098 (10th Cir. 2017) (similar).

Here, the Complaint and associated materials provide clear evidence that the FDA would have rejected Plaintiff's desired label change: the FDA approved a label explicitly denying that scientific evidence demonstrated any clinical consequences from the gadolinium retention Plaintiff claims. Specifically, in 2017, the FDA convened its Medical Imaging Drugs Advisory Committee ("MIDAC") to discuss "the potential risk of gadolinium retention in the brain and other body organs in patients receiving gadolinium-based contrast agents." *See* Ex. D, 8/18/2017 FDA Public Participation Information, Meeting of the MIDAC at 1, https://www.fda.gov/AdvisoryCommittees/Calendar/ucm571112.htm; *see also* Compl. p.12 ¶ 58 (noting September 2017 meeting). MIDAC received briefing and testimony from leading experts, as well as any

members of the public wishing to comment.[12] In attendance was Todd Walburg, Plaintiff's own attorney in this matter. Mr. Walburg attempted to convince MIDAC, on behalf of his clients, that GBCAs caused harm to patients with normal kidney function, and that a warning stating as much was necessary. *See* Ex. F, 9/8/2017 MIDAC Meeting Tr. at 293-300,[13] https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/MedicalImagingDrugsAdvisoryCommittee/UCM584442.pdf.

After hearing the evidence, the FDA approved a revised Magnevist label in July 2018 stating that "clinical consequences of gadolinium retention ***have not been established*** in patients with normal renal function."[14] The FDA's approval of this label—after thorough consideration of the very issue Plaintiff claims should have been included—is clear evidence that the FDA would have rejected Plaintiff's proposed warning. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1099, 1101-02 (10th Cir. 2017) (holding that "FDA's rejection of [a] citizen petition" requesting a warning, based on the agency's "evaluat[ion of] the scientific merit" of the request and "survey[of] the literature" relevant to the question, was "clear evidence" that the FDA would not have approved the requested warning); *Risperdal and Invega Product Liability Cases*, No. BC599531, 2017 WL 4100102, at *10 (Cal. Super. Ct. Mar. 16, 2017) ("The denial of the Citizens Petition . . . alone also serves to provide 'clear evidence' that the FDA was satisfied with the current . . . label . . . ."). That is particularly so because the FDA's approval of Magnevist's 2018 label reflected "the agency's formal, authoritative conclusions regarding the conditions under which

[12] *See* Ex. E, 9/8/2017 MIDAC Meeting Agenda at 1-3, https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/MedicalImagingDrugsAdvisoryCommittee/UCM577009.pdf.

[13] Exhibit F presents relevant excerpts of the transcript.

[14] *See* Ex. B, 7/25/2018 Revised Magnevist label at 4 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf.

[Magnevist] can be used safely and effectively," *Utts*, 226 F. Supp. 3d at 184, and required the agency to conclude "that [Magnevist's label was] not 'false or misleading in any particular.'" *In re Celexa*, 779 F.3d at 36. Since clear evidence shows the FDA would have rejected Plaintiff's desired warning, Plaintiff's claims are preempted on this additional ground.

C. Plaintiff Fails to State a Claim for Negligence or Strict Liability

Plaintiff fails to plead an injury allowing her to state a tort claim for negligence or strict liability under New York law. Plaintiff's so-called "primary injury alleged [in the Complaint] is gadolinium ***retention*** in multiple organs," meaning that trace amounts of gadolinium have allegedly remained in Plaintiff's body after using Magnevist. Compl. pp.1-2 ¶ 4 (emphasis added). The "retention" of gadolinium is not a legally cognizable injury under New York tort law. *See Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 14 (N.Y. 2013) ("[t]he requirement that a plaintiff sustain ***physical harm*** before being able to recover in tort is a fundamental principle of [New York's] tort system" (emphasis added) (citation omitted)). Plaintiff also alleges that "[t]he gadolinium . . . was retained in her body and resulted in fibrosis in her organs, skin, and bones . . . and related injuries." Compl. p.5 ¶ 24. But Plaintiff pleads nothing showing that "fibrosis" or "related injuries" in patients with normal renal function were reasonably foreseeable to Bayer, as is required for New York tort liability.[15] And Plaintiff's catch-all allegation of "related injuries" is too vague to satisfy pleading requirements, and thus cannot support either of her claims. Finally, both Plaintiff's negligence and strict liability claims are

[15] As explained in *supra* Section II.B, Plaintiff's allegation contradicts the FDA's public health advisory statements, along with the 2018 FDA-approved Magnevist label, which confirm that "clinical consequences of gadolinium retention have not been established in patients with normal renal function." Ex. B, 7/25/2018 Revised Magnevist label at 4, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf; Compl. p.2 ¶ 5.

pled vaguely and broadly, in violation of Fed. R. Civ. P. 8(a) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), which means they should be dismissed.

1. Plaintiff Fails to Plead an Injury Supporting Her Claims

a. Plaintiff's Allegation of Mere "Retention" of Gadolinium Fails to Plead a Legally Cognizable Injury

Plaintiff's allegation of "retention" of gadolinium—meaning that trace amounts remain in Plaintiff's body for some time without further symptoms—is not a legally cognizable injury. That is because "[t]he requirement that a plaintiff sustain ***physical harm*** before being able to recover in tort is a fundamental principle of [New York's] tort system." *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 14 (N.Y. 2013) (emphasis added) (citation omitted); *see also Kimbar v. Estis*, 135 N.E.2d 708, 709 (N.Y. 1956) (negligence claim requires "resultant injury to plaintiff"). In *Caronia*, the Court of Appeals held that plaintiffs failed to allege injury when they claimed that years of smoking cigarettes had "expos[ed them] to carcinogenic agents," particularly "tar," 5 N.E.3d at 19, and put them "at an increased risk for developing lung cancer," *id.* at 14 (quotation marks omitted). Here, Plaintiff similarly pleads that her "primary injury" is "gadolinium retention in multiple organs," Compl. pp.1-2 ¶ 4, that "Plaintiff was never warned about the ***risks*** of gadolinium retention," Compl. p.2 ¶ 5 (emphasis added), and that the phenomenon of retention "causes fibrosis in organs, bone, and skin," Compl. pp.1-2 ¶ 4. Plaintiff's claimed injury from gadolinium retention thus appears to be that it increases her ***risk*** of ***future*** injury. As *Caronia* explained, "[a] threat of future harm is insufficient to impose liability against a defendant in a tort context." 5 N.E.3d at 14, 18-19. Consequently, Plaintiff's allegation of mere gadolinium retention that may lead to future injuries cannot support a claim for either negligence or strict liability. *See also In re Ross*, 548 B.R. 632, 640 (Bankr. E.D.N.Y.

2016) ("injury" requirement in New York tort law "requires more than mere exposure to a defective product"), *aff'd sub nom. Mendelsohn v. Ross*, 251 F. Supp. 3d 518 (E.D.N.Y. 2017).

b. Plaintiff Fails to Plead That "Fibrosis" or "Related Injuries" Were Reasonably Foreseeable

Plaintiff fails to plead facts showing that any alleged "fibrosis in her organs, skin, and bones," and "related injuries," Compl. p.5 ¶ 24, were reasonably foreseeable, which means those purported injuries cannot support her negligence and strict liability claims. Bayer was required to "warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist," but had no duty to warn of unforeseeable dangers. *Martin v. Hacker*, 628 N.E.2d 1308, 1311 & n.1 (N.Y. 1993) (discussing requirements for strict liability claims and stating that "New York views negligence and strict liability claims as equivalent"); *see also McDonnell v. Chelsea Mfrs., Inc.*, 687 N.Y.S.2d 172, 174 (2d Dep't 1999) ("A manufacturer has the duty to warn of all potential dangers in its prescription drugs it either knows to exist or, in the exercise of reasonable care, should have known to exist."). Here, no allegations in the Complaint suggest that Bayer had the requisite knowledge that gadolinium retention from Magnevist posed "an unreasonable danger" for patients with normal kidney function. *See Daley v. McNeil Consumer Products Co.*, 164 F. Supp. 2d 367, 373 (S.D.N.Y. 2001) ("[T]o impose liability on the manufacturer requires knowledge that the product poses an ***unreasonable danger***." (emphasis added)). As noted in Section II.B, the FDA approved a 2018 Magnevist label stating that "clinical consequences of gadolinium retention have not been established in patients with normal renal function," which as pled includes Plaintiff, after conducting a thorough review of Magnevist's and other GBCAs' safety. *See* Ex. B, 7/25/2018 Revised Magnevist label at 4, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf. Likewise, the 2018 FDA-approved patient guide states "studies ***have***

not found harmful effects in patients with normal kidneys." *See* Ex. B, 7/25/2018 Revised Medication Guide at 12, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf. That label and patient guide followed repeated FDA statements, both before and after Plaintiff's Initial Complaint, to the same effect. *See supra* Section II.B.

Plaintiff's Complaint includes no facts showing that Bayer should have known of risks that the FDA confirmed "have not been established" after repeated, thorough, recent analyses. Plaintiff names no scientific development suggesting that gadolinium exposure from Magnevist causes fibrosis, or any other "related injuries," in persons with normal kidney function. *See* Compl. pp.5-13. Instead, Plaintiff's listed scientific developments largely relate to ***retention*** of trace amounts of gadolinium in patients' bodies after using GBCAs.[16] *See, e.g.*, Compl. pp.9-10 ¶¶ 45-47 (noting retention of gadolinium in humans); pp.11-13 ¶¶ 55-59 (noting studies finding evidence of retained gadolinium, and government action regarding retained gadolinium). The only developments relating to "fibrosis" are those concerning NSF, which is a condition that Plaintiff concedes by definition affects only persons with kidney impairments. *See, e.g.*, Compl. pp.10-11 ¶¶ 49-52 ("NSF . . . was defined as only occurring in patients with renal failure"). Any remaining "facts" are unsupported generalizations that do not show how Bayer could have known of the risks alleged here. *See, e.g.*, Compl. p.11 ¶ 54 ("patients sent several strongly worded letters with scientifically-supported research data to the FDA"). In short, Plaintiff pleads nothing showing that Bayer knew, or should have known, of the risks Plaintiff claims, especially in light of the FDA's statements concluding such risks "have not been established" in patients

[16] Other developments relate to general contentions about GBCA properties, and have nothing to do with the medicines' direct effects on humans. *See, e.g.*, Compl. pp.7-8 ¶¶ 37-41 (commenting on strength of gadolinium chelates and stability of GBCAs); pp.8-9 ¶¶ 40-44 (discussing deposition of gadolinium in animals).

who have normal kidney function. *See also* Compl. p.5 ¶ 24 (claiming Plaintiff "had normal kidney function").

c. Plaintiff's Allegation of "Related Injuries" Is Not Specific Enough to Satisfy Pleading Requirements

Further, Plaintiff's passing reference to "related injuries" does not satisfy pleading requirements. *See* Compl. p.5 ¶ 24 ("The gadolinium that Ms. McGrath was injected with was retained in her body and resulted in fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, ***and related injuries***." (emphasis added)); *see also* Fed. R. Civ. P. 8(a); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Pleadings may not consist of mere "labels and conclusions" or "naked assertions devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678 (brackets and quotation marks omitted). The term "related injuries" is just such a "naked assertion"—it does not put Bayer on notice of any particular harm, nor does it explain how such a harm was reasonably foreseeable at the time of Plaintiff's alleged injury. *See McDonnell*, 687 N.Y.S.2d at 174 (manufacturers have duty to warn of risks they knew or reasonably should have known). As such, this generalization cannot support Plaintiff's strict liability or negligence claim.

2. Plaintiff's Strict Liability and Negligence Claims Are Too Vague and Sprawling to Satisfy Pleading Rules

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 8, "a complaint must contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). Although "a court must accept as true all of the allegations contained in a complaint," that "tenet . . . is inapplicable to legal conclusions." *Id.* And per Rule 8(a), a plaintiff is required to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

Here, Plaintiff's scattershot negligence and strict liability claims fail pleading rules because they provide nearly three pages of vague, sprawling legal conclusions, without factual support, that do not put Bayer on notice of the actual claims pressed. For example, Plaintiff alleges that Bayer was negligent in the "design," "formulation," "manufacture," "sale," "testing," "***or*** distribution" of Magnevist, even though the Complaint contains no details alleging problems with these activities. *See* Compl. p.15 ¶ 73 (emphasis added). Plaintiff further states that Bayer "knew or should have known that these products could cause significant bodily harm or death, and were not safe for use by consumers," again without providing details as to particular tortious acts. *See* Compl. p.15 ¶ 73. Plaintiff's strict liability claim similarly alleges that Magnevist was "defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing." *See* Compl. p.14 ¶ 65. In other words, Plaintiff's allegation captures all wording in Magnevist's label at all times, and is not limited to any particular language or time period. These allegations are "so threadbare . . . that [they] fail[] to cross the line between the conclusory and the factual," and are thus "too meager, vague, [and] conclusory to survive a motion to dismiss." *Dejesus v. HF Mgmt. Servs., LLC*, 726 F.3d 85, 89 (2d Cir. 2013) (quotation marks omitted).

III. CONCLUSION

Plaintiff's claims fail for numerous reasons: Plaintiff fails to establish personal jurisdiction over Bayer, fails to plead facts showing her claims are not preempted, fails to plead an injury to support her claims, and does not plead sufficient factual material. Bayer respectfully requests that the Court dismiss Plaintiff's Amended Complaint with prejudice.

Dated: December 14, 2018

Respectfully submitted,

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